REMARKS

The present amendment is responsive to the Official Action mailed June 4, 2003. A petition for a three-month extension of the term for response to said Official Action, to and including December 4, 2003, is transmitted herewith.

Claims 10 and 12 were objected to under 37 C.F.R. § 1.75 as asserted failing to further limit the method steps recited in the parent claims. Claim 10 has now been amended to correct its dependency. As now amended, the claim clearly adds method steps to the recitations of claim 9; it includes a "providing" step as suggested by the Examiner. Claim 12 has been amended in substantially the manner suggested by the Examiner to overcome the objection, namely, by including recitations of "providing" the recited apparatus elements. It is, therefore, respectfully requested that the objection to claim 10 and 12 be withdrawn.

Claims 1-12 were provisionally rejected under the doctrine of obvious-type double patenting on co-pending Application Nos. 10/227,092; 09/905,227; and 10/062,693. The '227 application has now issued as U.S. Patent 6,635,054. A terminal disclaimer over the '054 patent is transmitted herewith and is believed to obviate the rejection on the basis of the '227 application. As to the rejections on the '092 and '693 applications, neither application has yet issued as a patent, and accordingly it is impossible for applicant to be certain that the claims which form the basis for the rejection will issue as patent claims. As further discussed below, applicant believes that the other rejections in the present case will be overcome by the present communication. In that event, the provisional double patenting rejections would remain as the only rejections in the case and would be automatically withdrawn. M.P.E.P. § 804, paragraph I.B.

Claims 1-3, 9 and 11-12 were rejected under 35 U.S.C. § 102(e) as "anticipated by or, in the alternative, under 35 U.S.C. § 103(a)" as unpatentable over *O'Connor*, U.S. Patent 6,398,792. By the present amendment, claims 1 and 9 have been amended to explicitly set forth that which was implicitly set forth in the expression "refractive surface," which has always been incorporated in each of these claims. Thus, each claim has now been amended to state that the refractive surface, in the inflated condition of the lens, defines an interface between media having different acoustic velocities. Support for this amendment is found in the words "refractive surface" themselves as originally and as the same would be understood by a person of ordinary skill in the art, and is additionally found at, *e.g.*, the passage quoted below from paragraphs 0027 and 0028:

> Lens balloon 717 is inflated by passing a fluid having acoustic velocity less than that of aqueous fluids but having acoustic impedance close to that of an aqueous fluid as, for example, a fluorocarbon, into the balloon through fitting 705, lumen 701 and port 719. Bearing balloon 711 is inflated with an aqueous fluid such as water or saline.

(Specification, ¶ 0027.)

. . . .

> Once again, the emitting element emits substantially cylindrical ultrasonic waves which propagate substantially radially as indicated by arrows 733 in FIG. 9. These waves are refracted at the interface formed by the different fluids in lens balloon 717 and bearing balloon 713 and bent towards the medial plane 721 as indicated by arrows 735 and hence focused into an annular focal region 737 concentric with central axis 724.

(Specification, ¶ 0028.)

Still further support is found from the passage quoted below from paragraph 0032:

> Here again, the lens balloon is filled with a fluid such as a fluorocarbon or other liquid having acoustic velocity lower than that of aqueous fluids but having acoustic impedance close to that of an aqueous fluid. The tissue of the vein wall has acoustic properties similar to those of water and other aqueous fluids. Accordingly, refraction of the acoustic waves occurs at the interface between lens balloon 717' and the vein wall tissue, so that the acoustic waves will be focused into a focal region 737' in a manner similar to that discussed above with reference to FIGS. 1 and 2.

(Specification, ¶ 0032.)

In the first embodiment (FIGS. 1, 2; ¶¶ 0027, 0028), the interface between media having different acoustic velocities is formed between the fluid disposed inside lens balloon 717, which has a lower acoustic velocity than that of an aqueous fluid and the aqueous fluid disposed in bearing balloon 711, outside of lens balloon 717. In the embodiment of FIG. 3 and paragraph 0032, the interface is formed between the low acoustic velocity fluid inside lens balloon 717' and the surrounding tissue which has "acoustic properties similar to those of water and other aqueous fluids." (Specification ¶ 0032.)

As the Examiner doubtless already appreciates, refraction of ultrasound occurs when sound passes from one medium having a first acoustic velocity and to another medium having a different acoustic velocity. *See, e.g.*, the brief summary of refraction of sound set forth in the Internet page "hyperphysics.phy-astr.gsu.edu\hbase\sound\refrac.html," annexed hereto as Exhibit A. This website is maintained by Georgia State University. Refraction of sound follows the same principles as refraction of light. As in refraction of light, the degree of refraction and the direction of refraction depend on the angle of incidence of the wave on the interface, and the difference in wave velocities (acoustic velocities, in the case of sound) in the media at the interface.

The Official Action does not offer any reason to believe that the balloon 22 shown in *O'Connor* defines a refractive surface forming an interface between media having different acoustic velocities.

O'Connor uses an "aqueous solution containing a contrast agent as an aid in viewing the process" (col. 3, lns. 39-41), *i.e.*, an aqueous solution including a radiological contrast agent, as the inflating fluid in its balloon. There is no suggestion or instruction in *O'Connor* to select the "aqueous solution" and the radiological "contrast agent" so that the solution with the contrast agent has any particular acoustic velocity, or indeed even a suggestion in the reference that it is possible to make an aqueous solution of a contrast agent with an acoustic velocity different from that of the surrounding tissue. As pointed out above, blood vessel tissues have acoustic properties "similar to those of water and other aqueous fluids." (Present specification ¶ 0032.)

Moreover, the reference leads directly away from any suggestion that the wall of the inflated balloon acts as a refractive surface. There is no discussion whatsoever as to the shape such an interface should have in order to refract the ultrasound in such a way that it would contribute to focusing of the ultrasound. The drawings show the inflated balloon 22 as a simple cylindrical device with a wall surface parallel to the emitting wall surface of transducer 24. Radially directed waves from a cylindrical transducer would strike such a cylindrical surface in a direction normal to the surface to itself and hence would not be refracted at all, even if one were to speculate that the acoustic velocities of the fluid in the balloon and the surrounding tissue were different from one another. Applicant does not here allege that the *O'Connor* disclosure requires such a cylindrical balloon. Rather, the point is that the *O'Connor* disclosure does not suggest that the shape of the balloon has

any influence on the asserted focusing action, and hence leads directly away from any inference that the balloon surface constitutes a refractive surface.

The allegation in the Official Action that "[i]t is inherent that the surrounding balloon containing a liquid/contract agent causing focusing of the ultrasonic waves constitutes an inflatable lens since it focuses the ultrasonic energy . . . " is respectfully traversed. First, the statements in *O'Connor* attribute the "focusing" to the aqueous solution contained inside the balloon, rather than to any refractive action at the balloon surface:

> The aqueous solution in the balloon 22 readily transmits and focuses energy to the thrombus . . .

(*O'Connor*, col. 3, lns. 44-46.) In that context, the asserted focusing action appears to be nothing more than transmission of ultrasonic energy to the tissue. No separate "focusing" is required in any of the claimed inventions in *O'Connor*. Moreover, "focusing" in the sense of *O'Connor* can occur without the use of a refractive interface. Merely by way of example, *Crowley*, U.S. Patent 5,630,837, of record, accomplishes focusing of ultrasound from a cylindrical transducer structure similar to that of *O'Connor* by controlling the phases of ultrasound emitted from various portions of the cylindrical transducer. In that context, the medium surrounding the cylindrical transducer also transmits and adds in the focusing of ultrasound, but without a refractive surface anywhere in the system. *O'Connor*'s "focusing" action is fully consistent with that type of "focusing."

The alternative allegation that, in *O'Connor*, the balloon serves as a "functional equivalent" to applicant's structure so as to produce "the same end result" does not establish either anticipation or obviousness. It does not demonstrate that one skilled in the art would be taught to make

a combination incorporating all of the structural features set forth in applicant's claim 1, or all of the method steps set forth in applicant's claim 9. Even if *O'Connor*'s structure somehow accomplishes focusing of the ultrasonic waves, that knowledge would not suggest to a person of ordinary skill in the art that the structure and method shown in the reference incorporates a refractive interface, or that such a structure could be, or should be, built with a refractive interface. The rejection of claims 1-3, 9 and 11-12 should be withdrawn.

Claims 4-8 and 10 were rejected under 35 U.S.C. § 103 as unpatentable over *O'Connor*. This rejection should be withdrawn for the same reasons as advanced above with respect to claims 1 and 9. Further, the allegation that the use of multiple balloons "filled with different media to create a refractive surface would have been a functional equivalent of a single balloon," as assertedly taught by *O'Connor*, is respectfully traversed. As pointed out above, there is no teaching in *O'Connor* of providing any refractive surface at all in the reference. There is no suggestion in the *O'Connor* reference that multiple balloons filled with different media would be advantageous, or even workable, to provide the actions sought by *O'Connor*.

Additionally, claim 10 specifically recites a method of operation in which the ultrasonic energy is refracted and concentrated into a relatively small axial extent (by the first-mentioned refractive surface and lens of claim 9), and additionally refracted after concentration so that the additionally refracted ultrasonic energy propagates substantially radially. This action is exemplified in FIG. 5 of the present drawings. The ultrasonic energy is refracted at surface 801 and thus concentrated into a band having an axial extent smaller than that of transducer 820. However, the ultrasonic energy is not allowed to continue in the direction

provided by surface 801. Instead, it is further refracted at surface 813 so that it propagates substantially radially from that surface, *i.e.*, from the "additional refractive interface" recited in claim 10. Nothing in any reference has been pointed out as suggesting a method in which ultrasonic energy is first refracted so as to form a narrow axial region, and then refracted again so as provide radial propagation.

As it is believed that all of the rejections and objections set forth in the Official Action have been fully met, favorable reconsideration is respectfully requested.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which she might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: December 4, 2003

Respectfully submitted,

By_____

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